

-- In general, the preferred controlled release coating materials which may be employed in the rate-controlling membrane of the compositions according to the invention include those which form a water-insoluble but water-permeable layer and from which release of drug is by diffusion through the layer. By "water-insoluble" we mean "sparingly soluble" as defined in British Pharmacopoeia (1988). By "water-permeable" we mean that at least 10% of water, held continuously in contact with the layer, will penetrate the layer within two hours (the degree of permeation may be measured in accordance with the techniques which are well known to those skilled in the art). The coating polymer may be inherently water-permeable or become water-permeable through the incorporation of other additives such as plasticisers or pore forming agents. Suitable coating polymers include methacrylate copolymers, ethylcellulose, etc. Preferred coating materials are the permeable, water insoluble grades of pharmaceutical polymethacrylates (Eudragit® RL100 (poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2), Eudragit RS100/RS30D (poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1), Eudragit NE30D (poly ethyl acrylate, methyl methacrylate) 2:1), Rohm Pharma, Darmstadt, Germany) and ethylcellulose. Eudragit RL100 and RS100 contain quaternary ammonium groups which may interact with ionised weakly acidic drugs and hence the most preferred coating materials are ethylcellulose and Eudragit NE30D. Ethylcellulose may be applied as a solution in an organic solvent or as a proprietary water-based latex preparation (e.g. Aquacoat®, FMC, Philadelphia, USA or Surelease®, Colorcon, West Point, USA). --

In the Claims:

Please cancel claims 1-17, 19, and 21-28, without prejudice.

Please add new claims 29-57 as follows:

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29. (New) A controlled release composition comprising  
(a) at least one pellet comprising an inner core coated with a rate-controlling membrane, wherein the membrane determines the rate of drug release, and wherein the inner core comprises a salt of a drug; and  
(b) means for preventing the release of a drug until the composition reaches a terminal ileum or a colon following oral administration of the composition, wherein the drug has a free acid group, a pKa in a range of 2.0 to 9.0, and is present in the